

Comparing the Efficacy of Alkaline Nasal Douches Versus Decongestant Nasal Drops in Postoperative Care After Septal Surgery: A Randomised Single Blinded Clinical Pilot Study

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Abstract To compare the efficacy of alkaline nasal douches and decongestant nasal drops following nasal septal surgery. This was a prospective, randomised, single-blind pilot study. Twenty patients were included in each arm of the study undergoing elective nasal septal surgery. The primary outcome measure was nasal congestion. Secondary outcome measures were anosmia, facial pain, nasal discharge, and sneezing/itching. This study does not show any statistically significant difference between the two treatment groups. Symptoms of nasal congestion ($P = 0.3$), facial pain ($P = 0.932$), nasal discharge ($P = 0.98$), sneezing ($P = 0.59$) and anosmia ($P = 0.208$) were analysed before conclusion. Three patients in saline group and one patient in the nasal drops group had poor compliance to follow the advice, scoring 2 on a VAS score but the treatment was tolerated well in majority of the patients. No statistical significant differences were noted on analysing the post operative complications in either group. In this study, both nasal douches and decongestant nasal drop were well tolerated. Both treatments provided good post-operative relief from nasal congestion, nasal discharge, sneezing, facial pain and anosmia as days progressed. The post operative examination of the nose among these patients revealed no significant complications in either of the study arm.

Keywords Nasal septal surgery · Nasal douches · Nasal drops

Introduction

Septal surgery is a common procedure performed in ENT practice. The commonest indication for undergoing this operation would be nasal blockage. This symptom could be inherited or secondary to a nasal trauma. Septal surgery will be in the form of septoplasty or submucosal resection.

Patients who have had such operations invariably will develop mucosal swelling, crusting and nasal discharge in the post operative period. These symptoms can last from few days to several weeks following the operation. To counter these problems patients are advised various forms of treatments. These could be in the form of nasal alkaline douches, nasal decongestants and or both.

Nasal alkaline douches have been a longstanding treatment for sinonasal disease. It has been practised in India for centuries as part of the purification routines performed in preparation for yoga [1]. Nasal irrigation with saline seems to reduce nasal and rhinosinusal dryness, facilitating the clearing of thick mucus and crusts in patient's affected by rhino sinusitis [2]. In addition to these properties, because of their effects of moisturisation, humidification and reduction of swelling, they have been tried after surgery for rhino sinusitis [3]. Nasal saline douches have been recommended in the immediate post operative period to clear the blood clots and crusts [4].

Nasal drops in the form of decongestants like ephedrine nasal drops and steroids like Betamethasone sodium phosphate 0.1% have been tried and tested with success [5]. Decongestant nasal drops (0.1% Xylometazoline hydrochloride) are potent sympathomimetic drugs which exert their effect by vasoconstriction of the mucosal blood vessels which in turn reduces oedema of the nasal mucosa. The purpose of this work is to provide data on which to design a study to compare the efficacy of the above two

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methods, and to assess the feasibility and likely utility of such a study.

Materials and Methods

This single-blind, randomised, clinical pilot trial was conducted at Royal Gwent Hospital between 2005 and 2006. Local and regional research and ethics committee approval was granted prior to the start of the study and informed consent taken from each participant.

Eligibility Criteria

Patients undergoing elective nasal septal surgery were enrolled into the study. Exclusion criteria were the patient being under the age of 18 years, patients unable or unwilling to give consent and those patients with relative contraindication for using nasal drops. Patients with haemostatic disorders were also excluded from the study.

Participant Allocation

Using a random sequence generated by a computer, patients were randomly assigned to have alkaline nasal douches or nasal drops.

Concealment of Allocation

The instructions for each patient were placed and sealed in sequentially numbered opaque envelopes, to be opened only on giving discharge advice.

Intervention

Patients were informed of the trial during the preoperative assessment visit. Written information regarding the trial was provided at this time and consent taken from those wishing to take part.

Operations were performed under general anaesthetic by different grades of surgeon. At the point of discharge on the following day an independent observer opened the next sealed allocation envelope and instructed the patient accordingly.

The recipe for alkaline nasal douche was given in printed format. Each time of use it was prepared fresh by taking one mug of warm tap water and dissolving half a teaspoon of table salt and quarter teaspoon of sodium bicarbonate. Patients were advised to pour a little of this mixture into cupped palm and sniff it through both nostrils, one at a time. They were advised to use a whole mug three times a day for 2 weeks.

Patients with nasal drops were advised to use two drops, three times a day for 2 weeks [6]. The participants were given the leaflet about the position of the head and neck on inserting the drops. This group of patients were prescribed xylometazoline hydrochloride 0.1% drops on discharge.

Blinding

Only the surgeon who examined the patients on post operative day 14 was blinded for the type of treatment received. Patients were instructed not to reveal about the treatment on their 14 day follow up period.

Outcome Measures

Our primary outcome measure was the nasal congestion in the post operative period. Patients were asked to record the severity of nasal blockage experienced each day on a graduated horizontal visual analogue scale, with a range of 0–10, 0 being no blockage and 10 representing total nasal obstruction. The scores were recorded each day for 14 days.

Our secondary outcome measures were facial pain, sneezing/itching, impaired smell and nasal discharge. Patients were asked to record the severity of these symptoms on a visual analogue scale each day for the 14 post operative days, on a scale ranging between 0 and 10, 0 being no problems and 10 being the worst experience.

Visual analogue scores are validated for assessing the severity of pain [7] and have been used previously to record the nasal symptoms [5].

The nasal cavities were examined using nasal endoscope at 2 weeks to assess the degree of discharge, oedema, crusting and scars or adhesion formation. Each of these findings were scored using modified form of Lund and Mackay staging system on a scale of 0–2 (oedema, scarring and crusting; 0: absent, 1: mild, 2: severe. Discharge; 0: no discharge, 1: thin discharge, 2: thick discharge). All recruited patients were examined by the same surgeon to avoid any bias. Patient compliance and tolerability with the advised treatment was also noted.

Power Calculations

Statistical support was obtained prior to the trial. A study using similar assessments was available to estimate expected effect sizes and group variability [8]. When devising this study, a two sided *t*-test with 80% power and 5% significance, a sample size of 20 per group would have a minimum detectable difference on the VAS assessments of 5.6 over the five VAS scores, or an average difference of 1.1 on a single VAS of 0–10.

Statistical Analysis

The difference in post operative nasal examination and findings were analysed with independent sample *t*-test. Repeated measures ANOVA was used for analysing the rest of the outcomes (VAS scores), with the assumption of linearity was shown to hold for all five variables, although there is evidence that a quadratic element was observable in nasal discharge. Statistical significance was accepted at the $P < 0.05$ level.

Results

Participants

Forty consecutive patients from the waiting list were entered into the trial. No patient refused entry or was excluded. Data was collected on all patients. Twenty were randomised to use nasal douches in the post operative period for 14 days. The remaining 20 patients used decongestant nasal drops in the post operative period. Table 1 shows the basic demographic characteristics of the two groups. Thirty-two patients were male and eight were female with no significant difference proportions between the two arms of the trial. The mean age of the patients were 44.4 years with a range of 21–68 years, again showing no significant differences in the two arms. The majority of patients (35 of 40) underwent septoplasty, and the remaining five patients underwent submucosal resection (SMR).

Outcomes

Primary

No significant differences ($P = 0.3$) were found in relieving nasal congestion between the two treatments over 14 days period (Fig. 1), although the visual analogue scale consistently shows the drops slightly below saline over the course of the 14 days. The group standard deviation for each day ranged from 1.886 on day 8 (mean 3.08) to 2.747 on the first day (mean 6.3). Although not statistically

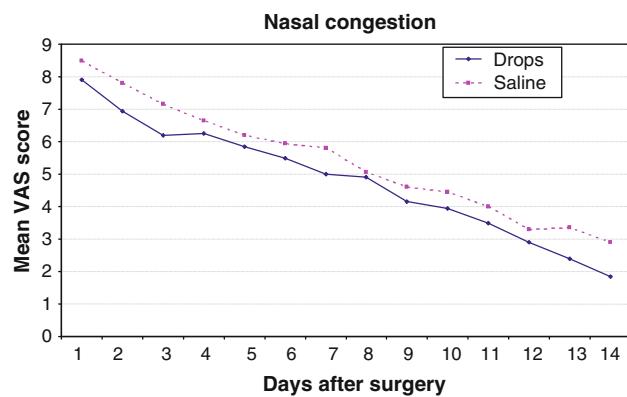


Fig. 1 Mean VAS for nasal congestion

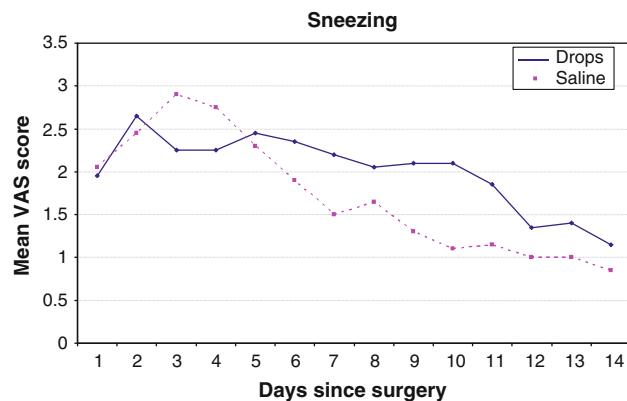


Fig. 2 Mean VAS for sneezing

significant, mean congestion using nasal drops was consistently about 0.5 below saline douche on every day of the follow-period. A trial to confirm a 0.5 point improvement on a VAS for nasal drops over saline would require 40 participants in each arm assuming the common standard deviation observed here.

Secondary

No significant difference was found in relieving sneezing ($P = 0.59$) and facial pain ($P = 0.932$) (Figs. 2, 3).

Figures 4 and 5 illustrate consistent but non significant differences between the two groups in favour of the drops, i.e. impaired smell ($P = 0.208$) and nasal discharge ($P = 0.098$). This would suggest that further investigation of the benefits of the drops over saline would be worthwhile.

At 2 weeks follow up clinic, scarring, crusting, oedema, or discharge was observed in each nostril and documented using modified Lund and Mackay scoring. Figure 6 illustrates the comparison of distribution of scores for each group in the left and right nostrils. Mean scores were computed and no significant differences were noted

Table 1 Baseline characteristics of both groups

	Treatment with drops	Treatment with douche	Significance of difference
Gender male	15	17	0.429
Age, mean (SD)	41.2 (12.1)	46.5 (12.7)	0.198
Operation septoplasty	18	17	0.999

SD standard deviation

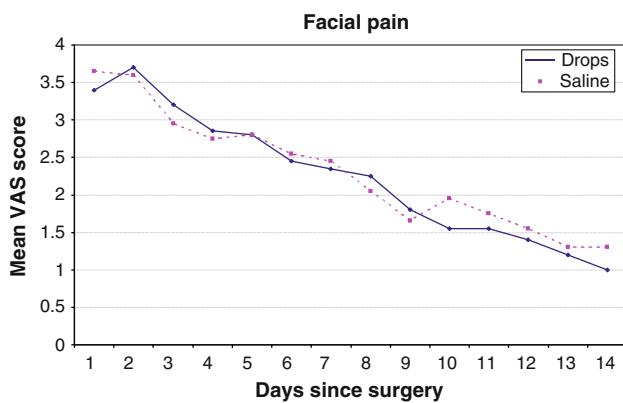


Fig. 3 Mean VAS for facial pain

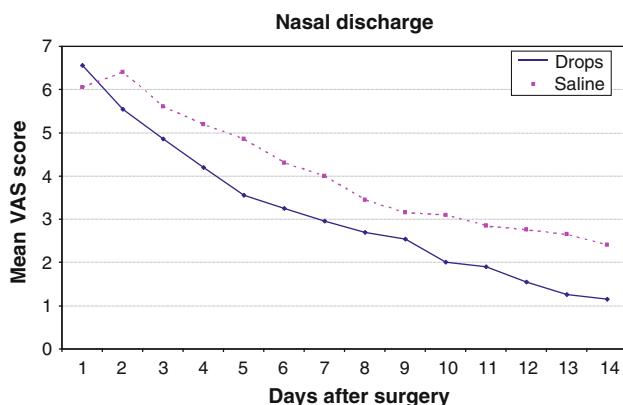


Fig. 4 Mean VAS for nasal discharge

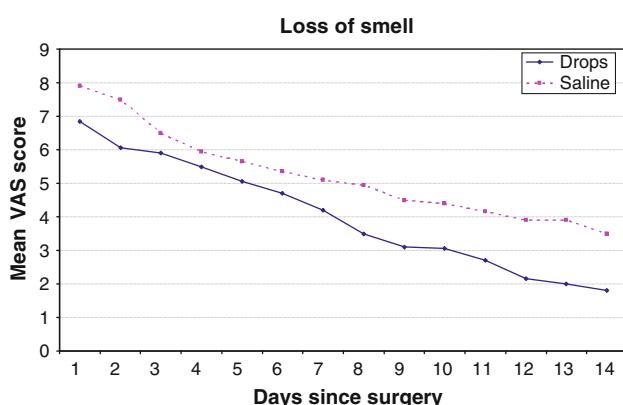


Fig. 5 Mean VAS for loss of smell

between the groups on either side (left $P = 0.695$, right $P = 0.412$).

Three patients, all in the saline group had poor compliance in following the trial directions (scoring 2 on a VAS score). The treatment in both arms of the trial was tolerated well in majority of patients, with 805 reporting a score of 10/10 for tolerability. The only participant to

record tolerability below 5 was one of the saline groups, who also reported poor compliance.

Adverse Events

No adverse events occurred among the patients in either group during the study period.

Discussion

Literature Review and Interpretation

A trial by Damien Pigret et al. compared pressurised sea-water versus and “chemical lavage” in managing post-ethmoidectomy crust formation [9]. The primary outcome of the trial was to measure the effectiveness of crust clearance from the nostrils after the treatment. Secondary outcome measures were symptoms like nasal obstruction, nasal discharge, cacosmia, facial pain and rhinitis like symptoms. No significant difference was observed among these two groups with regards to any of the symptoms.

Study by Seppey et al. compared rhinomer®, a cleansing preparation of isotonic, sterile, undiluted sea water, presented in a slightly pressurised bottle with no preservative nor CFC or Prorhinel®, an antiseptic solution. This study did not show any statistical difference in relieving the patient symptoms [8]. Primary outcome of this study was patient tolerability to the mode of treatment.

Passali et al. studied the nasal symptoms, comparing the atomised nasal douche and nasal lavage in acute viral rhinitis [10]. The study demonstrated more improvement in nasal symptoms with atomised nasal douche compared to nasal lavage.

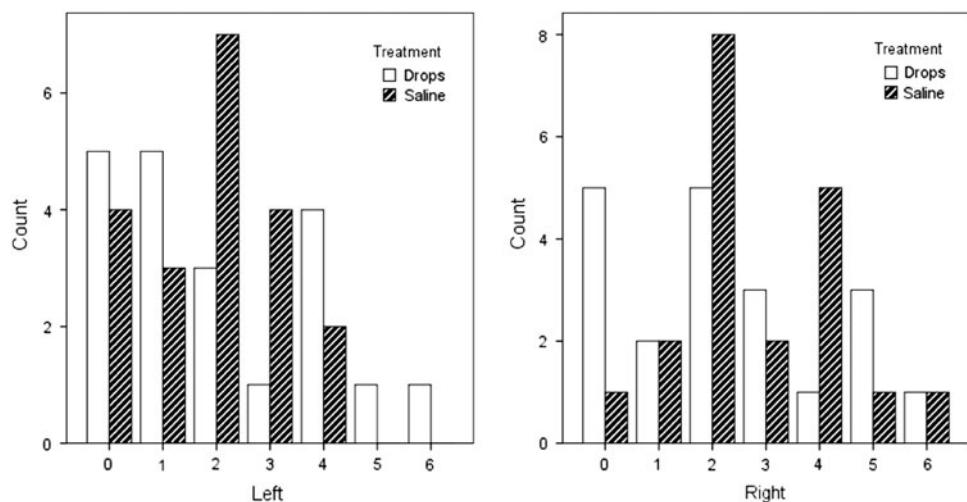
Spraggs et al. have demonstrated effectiveness and significant difference of ephedrine nasal drops in relieving the nasal congestion comparing to the control group who received no treatment [5].

Primary outcome of our study was about nasal congestion and we found that there was no statistical significance between the two modality of treatment. But, Fig. 1 clearly indicates that the patients using nasal drops had better and quicker relief of the nasal congestion.

Study by Passali et al. was comparing the pre and post treatment on acute viral rhinitis patient rather than two modalities of treatment. The score was recorded on a VAS of 0–3 unlike in our study.

Patient relief with nasal symptoms was progressively better in either of the arm. Nasal drops improved nasal congestion, nasal discharge and loss of smell as days progressed in the post operative period. Xylometazoline hydrochloride is a very potent sympathomimetic nasal drops, resulting in vasoconstriction of the nasal mucosa and

Fig. 6 Mean modified Lund and Mackay scores on each side in the treatment groups



reduction of the bulk of the turbinates. Hence the patients respond quickly with respect to the nasal congestion and in turn to the nasal discharge. Improvement in the sense of smell could be again probably related to the decongestant effect on the nasal mucosa along the roof of the nasal cavity. Both the modality of treatment was effective to relieve pain over 14 day period. Neither of the treatment had any inflammatory or anaesthetic effect which answers the findings in our study group.

Saline nasal douche improved sneezing episodes in patient more quickly when compared to the patients who used nasal drops. The only reason for this could be mechanical dislodgment of the crusts and clots and hence minimal nasal membrane stimulation (Fig. 3).

Three patients using nasal drops scored a score of 6 on one side (maximum 8 on modified Lund–Mackay score each side) and the rest of the scores were below 4 on each side.

Only one patient in saline douche arm scored a score of 6 on one side and the rest of the patients in this arm scored below 4 on each side. This indicates that saline douche is effective in reducing the oedema, crusting, discharge and in turn scarring when compared to the nasal drops. There was no statistical significance between the two modality of treatment on the ($P = 0.265$) right side unlike on the left side ($P = 0.045$).

This study also looked into the compliance and tolerability of the patient with the treatment and found that patients had more compliance with using the nasal drops, $P = 0.003$. Because nasal drops are available in ready to use container, it was more compliant with the patient. Only one patient scored 2 on a VAS of 10 but the rest scored 8–10.

Nasal saline douche was something patient had to prepare each time which would have reduced the compliance

with the patients. Three of 20 patients scored 2 on a VAS of 10, one scored 5 on a VAS of 10, and remaining patients scored 8–10. Newer ready to use saline irrigation container are now available to all the patients which would probably have improved the compliance rate with the patients.

The evaluation of any product being introduced into a health care system involves consideration of its cost. The nasal drops were priced at £1.91 per bottle [11] when compared to the home made saline douches.

Both groups tolerated the treatment well during the study period. Patients with low score with their compliance reflected their reduced tolerance to the treatment. Only two patients using nasal drops scored 5 on a VAS of 10, the rest of the patients tolerated well with the treatment scoring 10 on a VAS of 10. One patient in the nasal saline douche arm scored 2 on a VAS of 10, two patients scored 7 on a VAS of 10 and the remaining patients scored 10 on a VAS of 10. There was no statistical significance with the tolerability of the treatment between the two arms, $P = 0.476$.

It is interesting to note that our mean VAS score on the nasal symptoms were as high as eight on ten with gradual improvement during the 14 days period, compared to other studies [5, 9, 10]. There could be a number of reasons for this observed difference. It may relate to the type of nasal surgery performed, variation in VAS score and the overall methodology in each of the studies mentioned.

Our Study Design

Our study was purposely designed to include only septal surgery patients to maintain the uniformity with regards to nasal inflammation. We therefore avoided bias that would be incurred from differences in nasal inflammation that would have occurred in the post operative period.

We used the visual analogue scale for scoring as it is widely used, easily understood by most patients and readily reproduced on successive presentations. Its ratio scale properties lend itself to statistical analysis unlike multidimensional pain scales.

Same surgeon evaluated all the recruited patients on the 14th post operative day. The findings were recorded in the standard form after examination with a nasal endoscope. By doing this we have overcome the observational bias in this study.

Our Experience

We had very little difficulties in advising patients about the post operative treatment. In addition each patient was given a leaflet about the treatment and “how to do” to reinforce the advice.

Generalisability

Our study purposely permitted the inclusion of only patients with septal nasal surgery. As a result, the generalisability of the findings of this study should be limited to patients having this type of intervention.

Criticisms of Our Method

The study could be criticised for not evaluating patients undergoing other nasal surgery, which would be more likely to be associated with more nasal mucosal inflammation during the postoperative period, such as trimming of inferior turbinates or endoscopic sinus surgery. We advised our patients to use the decongestant nasal drops for 14 days [6] to maintain the uniformity within the two arms of the trial. We are aware decongestants are usually not used beyond 7 days, to prevent rebound congestion in the nose. If a similar trial were to be designed in the future we would suggest involving other nasal surgeries as well to obviate the risk of bias that could be incurred by not doing so. We would also avoid nasal decongestant beyond 7 days period to avoid any rebound nasal congestion. This is a pilot study and the power was calculated using an assumption, and hence the significance of the outcome is not statistically proven. If a similar study ought to be designed then the power has to be re-calculated to involve greater number of subjects in each arm. The small, non significant but consistent differences that we observed in the majority of the outcome variables would suggest that a further, larger study would be justified and further suggests that to confirm differences of approximately 0.5 on the visual analogue scales, with a repeat of the variability which we observed for nasal blockage of 2.1 would require approximately 65 people in each arm of a trial.

Conclusion

Both the nasal saline douche and the decongestant nasal drops improved nasal symptoms well in our study. They were well tolerated and complied by our patients in the post operative period.

In our trial, there was no statistical significant difference between the two arms of treatment. Nasal decongestant drops relieved nasal congestion quicker and better when compared to the saline douche. There were no significant complications or adverse effects on following this modality of treatments.

Bimodal treatment in the form of nasal decongestant drops and saline douche probably would benefit our post operative patients. There is scope for future trials along this line of management.

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Conflict of interest None.

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